SKILARENCE® (dimethyl fumarate) PRESCRIBING INFORMATION

Please consult the Summary of Product Characteristics (SmPC) before prescribing

Skilarence 30 mg & 120 mg gastro-resistant tablets

Active Ingredient: Skilarence 30 mg Each gastro-resistant tablet contains 30 mg dimethyl fumarate. **Skilarence 120 mg** Each gastro-resistant tablet contains 120 mg dimethyl fumarate. **Indication:** Treatment of moderate to severe plaque psoriasis in adults in need of systemic medicinal therapy. **Dosage and Administration:** For oral use. To improve tolerability, it is recommended to begin treatment with a low initial dose (30 mg tablet) and gradually increase or decrease the dosage in line with response and tolerability up to a maximum daily dose of 720 mg. *Consult SmPC and package leaflet for more information.* **Contraindications, Precautions, Warnings:** *Contraindications:* Hypersensitivity to the active substance or to any of the excipients. Severe gastrointestinal disorders, severe hepatic or renal impairment, pregnancy and breast-feeding. *Precautions:* Skilarence may decrease leukocyte and lymphocyte counts. No data available in patients with pre-existing low leukocyte or lymphocyte counts. A current complete blood count (including differential blood and platelet count) should be available before treatment initiation. Treatment should not be initiated if leukopenia $<3.0x10^9$/L, lymphopenia $<1.0x10^9$/L or other pathological results are identified. During treatment a complete blood count with differential should be performed every 3 months. *Leukopenia:* Discontinue treatment if the total number of white blood cells is $<3.0x10^9$/L. *Lymphopenia:* If the lymphocyte count falls $<1.0x10^9$/L but is $\geq 0.7\ x10^9$/L, perform monthly blood monitoring until levels return to $\geq 1.0x10^9$/L for two consecutive blood tests then monitor every 3 months. If the lymphocyte count falls $<0.7x10^9$/L, repeat the blood test and if these levels are confirmed, stop treatment immediately. Lymphopenia should be monitored after stopping treatment until the lymphocyte count has returned to the normal range. *Infections:* Treatment initiation should only be considered once a pre-existing infection has resolved. Consider suspending Skilarence if a patients develops an infection during treatment then reassess the benefits and risks prior to re-initiation of therapy. Patients on Skilarence should be instructed to report symptoms of infection. *Progressive multifocal leukoencephalopathy (PML):* Cases of opportunistic infections, particularly of PML have been reported. PML is an opportunistic infection caused by the John-Cunningham virus (JCV) that can be fatal or cause severe disabilities. Persistent moderate or severe lymphopenia during treatment with dimethyl fumarate is considered one of several risk factors for PML. Patients developing lymphopenia should be monitored for signs and symptoms of opportunistic infections, particularly if indicative of PML. If PML is suspected, Skilarence should be stopped immediately and neurological and radiological examinations performed. Renal and hepatic function should be checked prior to initiation of treatment and every three months thereafter. *Fanconi syndrome:* Early diagnosis and discontinuation of Skilarence treatment are important to prevent the onset of renal impairment and osteomalacia. *Flushing:* Likely to be experienced in the first few weeks of treatment. *Lactose:* Skilarence contains lactose. *Interactions:* Use with caution in combination with other systemic antipsoriatic therapy (e.g. methotrexate, retinoids, psoralens, ciclosporin, immunosuppressants or cytostatics). During treatment with Skilarence, simultaneous use of other fumaric acid derivatives (topical or systemic) should be avoided. Concurrent therapy with nephrotoxic substances (e.g. methotrexate, ciclosporin, aminoglycosides, diuretics, NSAIDs or lithium) may increase the potential for renal adverse reactions (e.g. proteinuria). Severe or prolonged diarrhoea during Skilarence treatment may affect the absorption of other medicinal products. Exercise caution when prescribing medicinal products with a narrow therapeutic index that require absorption in the intestinal tract. Avoid the consumption of large quantities of strong alcoholic drinks (> 30% alcohol by volume) which may increase the frequency of gastrointestinal adverse reactions. Skilarence has not been studied in patients with pre-existing gastrointestinal disease. Vaccination during treatment: No data available. Immunosuppression is a risk factor for the use of live vaccines. No evidence for Skilarence interaction with cytochrome P450. *Fertility, pregnancy and lactation:* Not recommended in women of child-bearing potential not using appropriate contraception. In patients experiencing diarrhoea during Skilarence treatment, the effect of oral contraceptives may be reduced and additional contraceptive methods may be necessary. There are limited data from the use of dimethyl fumarate in pregnant women. Animal studies have shown reproductive toxicity. Skilarence is contraindicated during pregnancy and breast-feeding. There are no human or animal data on the effects of Skilarence on fertility. *Ability to drive and use machines:* May have a minor influence. Dizziness and fatigue may occur. *Consult SmPC and package leaflet for more information.* **Adverse Reactions:** *Very common:* Lymphopenia, leukopenia, flushing, diarrhoea, abdominal pain and distention, nausea. *Common:* Eosinophilia, leukocytosis, headache, paraesthesia, vomiting, dyspepsia, constipation, abdominal discomfort, flatulence, decreased appetite, erythema, skin burning sensation, pruritus, fatigue, feeling hot, asthenia, hepatic enzyme increased. *Uncommon:* dizziness, proteinuria, serum creatinine increased. *Rare*: Allergic skin reactions. *Very rare:* Acute lymphatic leukaemia, irreversible pancytopenia. *Not known (cannot be estimated from available data):* PML, renal failure, Fanconi syndrome, herpes zoster. *Consult SmPC and package leaflet for more information.* **Legal Category: Ireland:** Subject to prescription which may not be renewed (A). **United Kingdom:** POM. **Price: Ireland -** 30 mg 42 tablets - €84; 120 mg 90 tablets - €187.20; 120 mg 180 tablets - €374.40. **United Kingdom: NHS Cost:** 30 mg - 42 tablets = £89.04; 210 tablets = £445.20; 120 mg - 90 tablets = £190.80, 180 tablets = £381.60 (excluding VAT). **Marketing Authorisation Number(s): IE & UK(NI) -** EU/1/17/1201/001, EU/1/17/1201/004, EU/1/17/1201/007. **UK(GB)**: PLGB 16973/0039 & PLGB 16973/0040. **Further information available from:** Almirall Limited, Harman House, 1 George Street, Uxbridge, Middlesex, UB8 1QQ, UK. **Date of Revision:** 03/2022. **Item code:** IE-IEDMF-2200002

UK-Adverse events should be reported.
Reporting forms and information can be found at MHRA
https://yellowcard.mhra.gov.uk
Adverse events should be also reported to
Almirall Ltd. Tel. 0800 0087 399

IE-Adverse events should be reported.
Reporting forms and information can be found at HPRA
Pharmacovigilance, Website: www.hpra.ie.
Adverse events should be also reported to
Almirall Ltd. Tel. +353 (0) 1431 9836